MOTION FILED
MAR 21 1980

No. 79-669

IN THE
Supreme Court of the United States
OCTOBER TERM, 1979

DAWSON CHEMICAL COMPANY, ET AL.,
Petitioners,
v.
ROHM AND HAAS COMPANY

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF FOR PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

PHILIP ELMAN
JOEL E. HOFFMAN
WILLIAM R. WEISSMAN
CAREY R. RAMOS
WALD, HARKRADER & ROSS
1300 Nineteenth St., N.W.
Washington, D.C. 20036

Attorneys for Pharmaceutical Manufacturers Association

BRUCE J. BRENNAN
EDWIN C. MULCAHY, JR.
1155 Fifteenth St., N.W.
Washington, D.C. 20005

Of Counsel

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

IN THE

Supreme Court of the United States

OCTOBER TERM, 1979

No. 79-669

DAWSON CHEMICAL COMPANY, ET AL.,
Petitioners,

v.

ROHM AND HAAS COMPANY

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

---

MOTION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATION FOR LEAVE TO FILE BRIEF AS AMICUS CURIAE

The Pharmaceutical Manufacturers Association (PMA) hereby moves, pursuant to Rule 42 of the Rules of this Court, for leave to file the attached brief as *amicus curiae*, urging affirmance. Respondent has consented to the filing of this brief; petitioners have withheld their consent.

PMA is a voluntary nonprofit association of 143 companies engaged in the discovery, development, manufacture and marketing of prescription drugs, medical devices and diagnostic products. PMA believes that the ex-

clusive rights conferred by the patent system provide an important incentive to the discovery and development of new therapeutic drugs and has, on behalf of its members, traditionally advocated the maintenance of those rights.[1]

This case poses a question of importance to all companies extensively involved in the research and development of new beneficial uses for previously discovered but unused chemical compounds. Specifically, this case will require the Court to decide whether the discoverer of such a new use must, unlike all other patentees, offer licenses to would-be competitors before it may enforce its patent rights against contributory infringement.

The answer to this question will be of special significance in the pharmaceutical industry, on behalf of which PMA consistently has opposed compulsory licensing of drug patents. Moreover, PMA members hold a number of method-of-use patents on therapeutic uses for unpatented, nonstaple compounds, and are actively engaged in screening such compounds for possible new therapeutic uses. The development of such drugs is plainly in the public interest, no less than the synthesis of new compounds. Yet there is widespread concern that new use research will not remain economically viable if the district court's decision, which cast doubt upon the enforceability of use patents for nonstaple compounds, is reinstated as petitioners urge.

Due to increasingly stringent regulatory requirements for pre-market testing and development, the average cost

[1] PMA has in the past filed briefs as *amicus curiae* in cases in this Court involving important patent and drug regulatory law issues. *Diamond* v. *Chakrabarty*, No. 79-136 (Oct. Term 1979), pending; *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973) and companion cases.

of developing a single new drug today is approximately $74 million.[2] Because of the considerable investment involved in deciding to develop a new drug, PMA members are particularly sensitive to changes in the patent law that may reduce the potential return and hence the incentive for pharmaceutical development. Pharmaceutical firms cannot afford to risk investing such enormous sums in the investigation of new therapeutic uses for known but unused compounds if legal barriers are erected against achieving a rate of return equal to that obtainable from the synthesis of new, patentable compounds. Consequently, if this Court requires compulsory licensing of new use discoveries as petitioners and the United States urge in this case, many previously unused compounds with promising but untested therapeutic value are likely to remain undeveloped.

The briefs and arguments of the parties will necessarily and properly focus on the particular facts and issues presented by this case. PMA's brief, on the other hand, focuses on three broader issues of law and public policy: (1) the basic and overriding intent of Congress in enacting section 271 of the Patent Act, 35 U.S.C. § 271, to encourage research and development of new uses for previously known but unused compounds, (2) the role of compulsory licensing in Congress' overall patent policy, and (3) the practical consequences of reversal on pharmaceutical innovation. These issues war-

[2] *See* Hansen, *The Pharmaceutical Development Process: Estimates of Development Costs and Times and the Effects of Proposed Regulatory Changes*, in ISSUES IN PHARMACEUTICAL ECONOMICS 151, 180 (R. Chien ed. 1979). Hansen calculated this cost as $54 million in 1976 dollars. The $74 million figure is the same estimate in current dollars.

rant consideration by the Court in its resolution of the instant case.

Respectfully submitted,

PHILIP ELMAN
JOEL E. HOFFMAN
WILLIAM R. WEISSMAN
CAREY R. RAMOS
WALD, HARKRADER & ROSS
1300 Nineteenth St., N.W.
Washington, D.C. 20036

Attorneys for Pharmaceutical Manufacturers Association

BRUCE J. BRENNAN
EDWIN C. MULCAHY, JR.
1155 Fifteenth St., N.W.
Washington, D.C. 20005

Of Counsel

March 21, 1980

TABLE OF CONTENTS

	Page
INTEREST OF AMICUS CURIAE	1
INTRODUCTION AND SUMMARY OF ARGUMENT	2
ARGUMENT	5
I. CONGRESS INTENDED SECTION 271 TO RESTORE THE STIMULUS REMOVED BY *MERCOID* TO INVESTIGATE AND DISCOVER NEW USES FOR NONSTAPLE COMPOUNDS.	5
II. SECTION 271 DOES NOT REQUIRE COMPULSORY LICENSING OF USE PATENTS...	10
III. THE FIFTH CIRCUIT'S HOLDING IS IMPORTANT FOR THE CONTINUED DISCOVERY OF NEW THERAPEUTIC DRUGS...	13
A. The Incentives to Pharmaceutical Innovation Are Currently in Decline.	14
B. Reversal of the Fifth Circuit's Holding Would Substantially Curtail Discovery and Development of New Therapeutic Uses For Known, Nonstaple Compounds.	18
CONCLUSION	23
APPENDIX	1a

TABLE OF AUTHORITIES

CASES: Page

Adams v. *Burke*, 84 U.S. (17 Wall.) 453 (1873) .. 9
Aro Manufacturing Co. v. *Convertible Top Replacement Co.*, 365 U.S. 336 (1961) 6
Aro Manufacturing Co. v. *Convertible Top Replacement Co.*, 377 U.S. 476 (1964) 2, 6, 9
Besser Manufacturing Co. v. *United States*, 343 U.S. 444 (1952) 12
Carbice Corp. v. *American Patents Development Corp.*, 283 U.S. 27 (1931) 3, 8
Continental Paper Bag Co. v. *Eastern Paper Bag Co.*, 210 U.S. 405 (1908) 11
Hartford-Empire Co. v. *United States*, 323 U.S. 386 (1945) 11
Henry v. *A.B. Dick Co.*, 224 U.S. 1 (1912) 2
Leeds & Catlin Co. v. *Victor Talking Machine Co.*, 213 U.S. 301 (1909) 2, 8
Mercoid Corp. v. *Mid-Continent Investment Co.*, 320 U.S. 661 (1944) 3, 4, 5, 7, 8, 9
Pfizer, Inc. v. *Califano*, Civ. No. 79-0185 (D.D.C. Jan. 23, 1979) 21
Sinclair & Carroll Co. v. *Interchemical Corp.*, 325 U.S. 327 (1945) 16
United States v. *Glaxo Group Ltd.*, 410 U.S. 52 (1973) 12
United States v. *Rutherford*, 442 U.S. 544 (1979) 14
United States v. *Univis Lens Co.*, 316 U.S. 241 (1942) 9

CONSTITUTION, STATUTES AND REGULATIONS:

U.S. CONST., art. I, § 8 3

Air Pollution Prevention and Control Act,

42 U.S.C. §§ 1857 *et seq.* 12

Copyright Act,

17 U.S.C. §§ 101 *et seq.* 12

TABLE OF AUTHORITIES—Continued

Page

Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 781,

§ 102(b), 21 U.S.C. § 455(b) 14
§ 102(c), 21 U.S.C. § 355(d) 14
§ 106(b), 21 U.S.C. § 355(i) 14

Patent Act of 1952,

35 U.S.C. § 154 ..... 11, 16
35 U.S.C. § 271 ..... 3, 4, 5, 6, 7, 9, 10, 11, 12
35 U.S.C. § 271(c) 3, 6, 9, 10
35 U.S.C. § 271(d) 4, 6, 8, 9, 10

Plant Variety Protection Act,

7 U.S.C. §§ 2321 *et seq.* 12

Sherman Act,

15 U.S.C. § 1 12

Regulations:

41 C.F.R. § 3-4.6104-2 (1979) 21
45 C.F.R. §§ 19.1-19.6 (1979) 21
45 C.F.R. § 19.1(a)(3) (1979) 21
45 C.F.R. § 19.5(c) (1979) 21
43 Fed. Reg. 57972 (1978) 21

LEGISLATIVE MATERIALS:

S. 300, 45th Cong., 1st Sess. (1877) 11
S. 2116, 62d Cong., 1st Sess. (1911) 11
S. 2303, 77th Cong., 2d Sess. (1942) 11
S. 2730, 77th Cong., 2d Sess. (1942) 11
S. 1552, 78th Cong., 2d Sess. (1962) 12
S. 814, 94th Cong., 1st Sess. (1975) 11, 12
H.R. 8776, 62d Cong., 1st Sess. (1911) 11
H.R. 26185, 62d Cong., 2d Sess. (1912) 11
H.R. 1371, 78th Cong., 1st Sess. (1943) 11
H.R. 5988, 80th Cong., 2d Sess. (1948) 5, 9
H.R. 3866, 81st Cong., 1st Sess. (1949) 9

S. REP. No. 1744, 87th Cong., 2d Sess., *reprinted in* [1962] U.S. CODE CONG. & AD. NEWS 2884 ... 12

TABLE OF AUTHORITIES—Continued

Page

Contributory Infringement in Patents—Definition of Invention: Hearings on H.R. 5988, H.R. 4061, and H.R. 5248 Before Subcommittee on Patents, Trademarks, and Copyrights of the House Committee on the Judiciary, 80th Cong., 2d Sess. (1948) 5, 6, 7, 8, 9, 11, 19

Contributory Infringement: Hearings on H.R. 3866 Before Subcommittee No. 4 of the House Committee on the Judiciary, 81st Cong., 1st Sess. (1949) 6, 8, 9, 10, 11

Drug Industry Antitrust Act: Hearings on S. 1552 Before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 87th Cong., 1st Sess. (1961) 12

Patent Law Codification and Revision: Hearings on H.R. 3760 Before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess. (1951) 6, 8, 9

LEGISLATIVE REFERENCE SERVICE, COMPULSORY LICENSING OF PATENTS: A LEGISLATIVE HISTORY (Senate Patent Study No. 12, 1958) 12

MISCELLANEOUS:

Baily, *Research and Development Costs and Returns: The U.S. Pharmaceutical Industry*, 81 J. POL. ECON. 70 (1973) 13

CENTER FOR THE STUDY OF DRUG DEVELOPMENT, PATENT DATA—1976-78 U.S. NCE APPROVALS (Annual Surveys 1978-80) 17

Clymer, *The Changing Costs and Risks of Pharmaceutical Innovation*, in THE ECONOMICS OF DRUG INNOVATION (J. Cooper ed. 1969) 14

Clymer, *The Economic and Regulatory Climate: U.S. and Overseas Trends*, in DRUG DEVELOPMENT AND MARKETING 137 (R. Helms ed. 1975) 15

TABLE OF AUTHORITIES—Continued

Page

Clymer, *The Economics of Drug Innovation*, in THE DEVELOPMENT AND CONTROL OF NEW PRODUCTS (M. Pernarowski & M. Darrack ed. 1971) .. 17

H. GRABOWSKI, DRUG REGULATION AND INNOVATION (1976) 13, 14, 15

Hansen, *The Pharmaceutical Development Process: Estimates of Development Costs And Times and the Effects of Proposed Regulatory Changes*, in ISSUES IN PHARMACEUTICAL ECONOMICS 151 (R. Chien ed. 1979) 15, 16

Kitch, *The Patent System and the New Drug Application: An Evaluation of the Incentives for Private Investment in New Drug Research and Marketing*, in REGULATING NEW DRUGS 82 (R. Landau ed. 1973) 16, 17

Lasagna & Wardell, *The Rate of New Drug Discovery*, in DRUG DEVELOPMENT AND MARKETING 155 (R. Helms ed. 1975) 17, 18

J. MARKHAM, PATENTING AND LICENSING POLICY AND PRIVATE SECTOR PARTICIPATION IN ENERGY RESEARCH AND DEVELOPMENT (1977) 20, 21

Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 J. POL. ECON. 1049 (1973) 14, 15

Peltzman, *The Benefits and Costs of New Drug Development*, in REGULATING NEW DRUGS 113 (R. Landau ed. 1973) 13, 14, 15

REPORT OF THE PRESIDENT'S COMMISSION ON THE PATENT SYSTEM (1966) 16

Sarett, *FDA Regulations and Their Influence on Future R&D*, RESEARCH MANAGEMENT, March 1974 17

D. SCHWARTZMAN, INNOVATION IN THE PHARMACEUTICAL INDUSTRY (1976) 13, 15, 16, 17, 20, 21

W. WARDELL & L. LASAGNA, REGULATION AND DRUG DEVELOPMENT (1975) 15

Wardell, *Therapeutic Implications of the Drug Lag*, CLINICL PHARMACOLOGY AND THERAPEUTICS, Jan. 1974 15

IN THE

Supreme Court of the United States

OCTOBER TERM, 1979

No. 79-669

DAWSON CHEMICAL COMPANY, ET AL.,
Petitioners,

v.

ROHM AND HAAS COMPANY

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

---

BRIEF FOR THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION AS AMICUS CURIAE

INTEREST OF AMICUS CURIAE

The Pharmaceutical Manufacturers Association (PMA) is a voluntary nonprofit association of 143 companies engaged in the discovery, development, manufacture and marketing of prescription drugs, medical devices and diagnostic products. PMA believes that the exclusive rights conferred by the patent system provide an important incentive to the discovery and development of new therapeutic drugs and has, on behalf of its members, traditionally advocated the maintenance of those rights.

This case presents a question of particular importance to the pharmaceutical industry. Specifically, this case will require the Court to decide whether the discoverer of a beneficial use for a compound with no prior commercial value must, unlike all other patentees, offer licenses to its competitors before it may enforce its patent rights against contributory infringement.

The answer to this question will materially influence the future viability of research in the phramaceutical industry aimed at developing therapeutic applications of previously undeveloped compounds. If this Court requires compulsory licensing of new use discoveries, as petitioners and the United States urge in this case, many previously unused compounds with promising but untested therapeutic value are likely to remain unused.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case involves the construction of a statute aimed at reconciling two important principles of patent and antitrust law that, in the context of this case, appear to collide. The law of patents has long recognized that it is impossible, as a practical matter, for a manufacturer who owns a patent for a method of use or for a combination of unpatented components to police direct infringement by a multitude of individual consumers who purchase the necessary components from another manufacturer and practice the method or assemble the combination themselves. *See, e.g., Aro Manufacturing Co.* v. *Convertible Top Replacement Co.*, 377 U.S. 476, 511-12 (1964). In response to this problem, this Court developed the doctrine of contributory infringement, which permits the patentee to sue a competing manufacturer who sells an unpatented component knowing it will be used in an infringing manner. *See Henry* v. *A.B. Dick Co.*, 224 U.S. 1 (1912); *Leeds & Catlin Co.* v. *Victor Talking Machine Co.*, 213 U.S. 301 (1909). Coming from the

opposite direction, however, and drawn from the policy underlying the antitrust laws is the doctrine first announced by this Court in *Carbice Corp.* v. *American Patents Development Corp.*, 283 U.S. 27 (1931), that "the owner of a patent may not employ it to secure a limited monopoly of an unpatented material used in applying the invention." *Mercoid Corp.* v. *Mid-Continent Investment Co.*, 320 U.S. 661, 664 (1944).

In *Mercoid*, this Court appeared to resolve that conflict in favor of the antitrust principle of "misuse" articulated in the *Carbice* case. Writing for the Court, Mr. Justice Douglas stated broadly that in any conflict between the two principles—the one based upon the Patent Clause ("To promote the Progress of Science and useful Arts, by securing for limited times to . . . Inventors the exclusive Right to their . . . Discoveries," U.S. CONST., art. I, § 8) and the other extracted from the unexpressed premises of the Sherman Act—the antitrust prohibition against misuse must prevail. *Id.* at 669. In the years 1948 to 1952, however, Congress reviewed and revised the simplistic preference given to antitrust in *Mercoid*. Striking a middle ground, Congress plainly declared in section 271 of the Patent Act of 1952, 35 U.S.C. § 271, that in those cases where the unpatented article is not a staple, the doctrine of contributory infringement shall prevail over any claim of misuse arising from a patentee's suit to enforce its rights against contributory infringers.

Congress arrived at this compromise in two steps. First, section 271(c) limits the doctrine of contributory infringement to the unauthorized sale of a nonstaple "article or commodity of commerce [un]suitable for substantial noninfringing use." No one disputes that the petitioners' sale of propanil, a nonstaple "[un]suitable for substantial noninfringing use," constitutes contributory infringement as defined by section 271(c). Second,

section 271(d) provides that a court shall not find that a method-of-use patentee has misused its patent because it has (1) sold an unpatented article for use in the patented method, (2) licensed its method of use, (3) sued others for contributory infringement, or done any combination of these things.

Rohm and Haas has done precisely what section 271(d) permits: sold propanil and sued unlicensed manufacturers of propanil for contributory infringement. Although it has not expressly licensed anyone to practice the method, its buyers are authorized to practice the method by operation of law. Petitioners nonetheless contend that section 271(d) does not expressly permit Rohm and Haas to refuse to license competing manufacturers. But the exclusive right of patentees to practice their inventions, and hence to license or refuse to license others, selectively or across the board, is the very essence of the patent right. There is nothing in section 271 that expresses an intent by Congress to deny that fundamental right to method-of-use patentees. To the contrary, the legislative history and background of the 1952 Patent Act show that Congress deliberately tipped the scales away from *Mercoid*, with its antitrust tilt, and reestablished the doctrine of contributory infringement as to nonstaples. To hold otherwise would be to depart from the balance struck by Congress in the 1952 Patent Act. To side with petitioners' antitrust views would amount to judicially imposed compulsory licensing. Congress' long-standing patent policy, however, strongly disfavors compulsory licensing of patents.

ARGUMENT

I. CONGRESS INTENDED SECTION 271 TO RESTORE THE STIMULUS REMOVED BY *MERCOID* TO INVESTIGATE AND DISCOVER NEW USES FOR NONSTAPLE COMPOUNDS.

The essence of this case is that section 271 of the Patent Act of 1952 is not an antitrust statute but a patent statute designed to remove from the patent laws what was perceived to be an inappropriate antitrust gloss placed on the patent law doctrine of contributory infringement by Mr. Justice Douglas' opinion in *Mercoid*. The purpose of section 271 was clear from its inception. The Patent Law and Practice Committee of the New York Patent Law Association, chaired by Giles S. Rich (now Associate Judge of the United States Court of Customs and Patent Appeals), convened in 1946 to prepare a bill to erase the damage done by *Mercoid* by codifying the doctrine of contributory infringement as it had been understood and applied for almost a half-century prior to that case.

The Committee drafted the bill over the next two years and Judge Rich testified as its sponsor at hearings before the House Subcommittee on Patents, Trademarks, and Copyrights in May 1948.[1] At the outset of these

[1] The contributory infringement provisions of the original bill, H.R. 5988, read as follows:

> Sec. 3. The sale of a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, if especially made or adapted for use in infringement of such patent, and not suitable for actual commercial noninfringing use, shall constitute contributory infringement.
>
> Sec. 4. The mere sale of any staple article or commodity of commerce not especially made or adapted for use in a patented invention, and suitable for actual commercial noninfringing use, shall not of itself constitute contributory infringement,

hearings, Judge Rich, whose testimony this Court has recognized as the chief authority in interpreting section 271,[2] submitted a statement on behalf of the New York Patent Law Association describing the bill and its pur-

---

even though sold with the knowledge or expectation that it will be used in infringement of the patent.

Sec. 5. No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent monopoly because he has done one or more of the following: (a) Derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (b) licensed or authorized one or more persons to perform acts which if performed without his consent would constitute contributory infringement of the patent; (c) sought to enforce his patent rights against infringement or contributory infringement.

Contributory Infringement in Patents—Definition of Invention: Hearings on H.R. 5988, H.R. 4061, and H.R. 5248 Before Subcomm. on Patents, Trademarks, and Copyrights of the House Comm. on the Judiciary, 80th Cong., 2d Sess. 1 (1948) [hereinafter cited as *1948 Hearings*]. As Judge Rich testified in subsequent hearings, sections 3 and 4 of the original bill were combined to form what is now section 271(c). Section 5 became section 271(d) with only minor changes in language: "patent monopoly" to "patent right" and "because he has done" to "by reason of his having done." *See Patent Law Codification and Revision: Hearings on H.R. 3760 Before Subcomm. No. 3 of the House Comm. on the Judiciary*, 82d Cong., 1st Sess. 151-52 (1951) [hereinafter cited as *1951 Hearings*]. The 1948 bill was reintroduced without change in the next Congress as H.R. 3866, and appears in *Contributory Infringement: Hearings on H.R. 3866 Before Subcomm. No. 4 of the House Comm. on the Judiciary*, 81st Cong., 1st Sess. 1 (1949) [hereinafter cited as *1949 Hearings*].

[2] *See Aro Mfg. Co.* v. *Convertible Top Replacement Co.*, 377 U.S. 476, 486 n.6, 511 (1964); *Aro Mfg. Co.* v. *Convertible Top Replacement Co.*, 365 U.S. 336, 347 n.1, 348 n.3, 349 n.4, 365 n.9, 366-67, 378-79 n.7 (1961). The subcommittee that held hearings in 1951 and the Congress that enacted the 1952 Patent Act were plainly aware of Judge Rich's testimony on contributory infringement at the 1948 and 1949 hearings. *See 1951 Hearings* 151-52. And this Court has considered the purpose of the 1948 and 1949 bills in interpreting section 271 as finally codified. *Aro Mfg. Co.* v. *Convertible Top Replacement Co.*, 377 U.S. at 511.

pose.[3] "The purpose of the bill," wrote Judge Rich, "is to restore the stimulus of the patent system to large and important fields of inventive effort which have, in practical effect, been placed outside the patent law by recent decisions of the Supreme Court abolishing effective protection against contributory infringement." *1948 Hearings* 3.

Judge Rich cited two major types of invention that had been discouraged by this Court's decisions, "[d]iscovery of new uses" and "combination patents." He expressed particular concern that the decision in *Mercoid* had withdrawn the stimulus for the discovery of new uses. "In chemical research," Judge Rich indicated, "a new and commercially important result is not infrequently obtained by the use of chemical compounds which have previously existed but have not been put to any practical use." *Id.* at 5. Indeed, Judge Rich concluded that it was "probable" that a chemist searching for a compound to solve a scientific problem would "find somewhere in the chemical literature a description of the compound which he has found necessary for this purpose." *Id.*

In that circumstance, the chemist could not obtain a composition patent for the chemical and would have to rely instead on a process or method patent for protection. But, as Judge Rich testified, such patents were not enforceable, for *Mercoid* precluded a suit for contributory infringement and "[a]s a practical matter, no patentee [could] afford to attempt to protect . . . his invention by suing all the innocent members of the public who have been induced to use it." *Id.* Thus, Judge Rich concluded, "the stimulus of the patent system [was] withdrawn from this class of inventions"; section 271 was specifically designed to restore that incentive with respect

---

[3] The portion of Judge Rich's statement concerning the discovery of new uses is reproduced in the Appendix at pp. 1a-3a *infra*.

to nonstaples while leaving *Mercoid* intact as to staples. *Id.* at 5-6.[4]

Judge Rich's sponsoring statement precisely foreshadows the facts of this case. Rohm and Haas has developed and patented a new use for the nonstaple propanil and seeks to do just what section 271(d), as conceived by its chief draftsman, would have it do, *i.e.*, sell propanil and sue unlicensed sellers for contributory infringement.[5] Without these rights, the stimulus for developing new uses is withdrawn. As Judge Rich emphasized in his testimony, the only practical way to enforce a patent for the use of a nonstaple chemical is to sue those who sell the chemical knowing that its buyers will use it in an infringing manner. *1948 Hearings* 5. That is precisely what sections 271(c) and (d) authorize the patentee to do.[6]

Despite the parties' stipulation (Pet. App. 38) that Rohm and Haas sells only propanil and that its purchasers are authorized to practice its patent not by express license but by operation of law,[7] the United States insists on treating Rohm and Haas as if it marketed two separate products and has conditioned the availability of one on the purchase of the other (U.S. Br. at 6-7). In essence, the Justice Department, as *amicus curiae*, asks this Court to ignore the stipulated facts and rewrite section 271 to preserve *Mercoid* as it urged unsuccessfully before Congress some 30 years ago. Congress rejected the Department's arguments then and the Court should not entertain them now.[8]

---

[4] The petitioners have characterized Judge Rich's testimony as unclear. But under careful questioning by Congressman Willis in the 1949 Hearings, Judge Rich stated unambiguously that "[t]he exception which we wish to make to the misuse doctrine would reverse the result in the *Mercoid* case." *1949 Hearings* 67. Congressman Willis asked Judge Rich to repeat this statement, which he did. *1949 Hearings* 68. Mr. Willis then asked Judge Rich to explain the effect of the proposed bill on the misuse doctrine. At this point, Judge Rich proceeded by illustration to demonstrate that the bill would preserve the doctrine in cases like *Carbice* involving the sale of "staple commodities of commerce," but preclude its application in cases like *Leeds & Catlin Corp.* v. *Victor Talking Machine Co.*, 213 U.S. 301 (1909), involving nonstaples. At the conclusion of this testimony, Mr. Willis stated that Judge Rich had made himself "entirely clear." *1949 Hearings* 73.

Had the Committee not intended the result Judge Rich stated so precisely in the 1949 hearings, presumably it would have revised the misuse section of the bill to expressly preserve the misuse doctrine with respect to nonstaples when it redrafted the bill for consideration at the 1951 hearings. Its failure to revise the misuse provision, in the face of so clear a statement of its purpose by the chief draftsman, strongly implies the Committee's satisfaction with Judge Rich's construction. *See 1951 Hearings* 13.

[5] Rohm and Haas does not thereby remove propanil from the public domain, as the district court believed (Pet. App. 89) and petitioners contend (Pet. Br. at 33). Although technically not patentable as a composition of matter for lack of novelty, propanil was worthless before Rohm and Haas discovered its value as a herbicide. Whatever market now evists for propanil was created by Rohm and Haas' invention. Prior to that invention, others were free to discover new uses of the compound and market it for those uses. They remain free to do so.

[6] Indeed, as this Court recognized in *Aro Mfg. Co.* v. *Convertible Top Replacement Co.*, 377 U.S. 476, 511 (1964), the 1948 and 1949 bills were entitled "Bills To Provide For The Protection of Patent Rights Where Enforcement Against Direct Infringers Is Impracticable." H.R. 5988, 80th Cong., 2d Sess. (1948); H.R. 3866, 81st Cong., 1st Sess. (1949).

[7] *See Aro Mfg. Co.* v. *Convertible Top Replacement Co.*, 377 U.S. 476, 497 (1964); *United States* v. *Univis Lens Co.*, 316 U.S. 241, 249 (1942); *Adams* v. *Burke*, 84 U.S. (17 Wall.) 453, 456 (1873).

[8] Testifying on behalf of the Justice Department at the 1949 hearings, Mr. John C. Stedman objected to the language of section 271(d). "Its effect," Stedman stated, "is to permit a patentee to sell unpatented parts for a device or composition covered by his patent or sell unpatented materials or apparatus for use with a process patented by him, and at the same time prohibit his competitors from selling such unpatented materials in competition with him." *1949 Hearings* 52. *See 1951 Hearings* 97, 165, 168-69, 207. The subcommittee recalled Judge Rich to respond to Mr. Stedman's testimony. Judge Rich stated that he agreed with Mr. Stedman's interpretation of the misuse provision of the bill but that the

Following a slightly different approach, petitioners in effect urge, as the district court concluded,[9] that patentees should be required to offer licenses to competitors before they may sue to enjoin contributory infringement.[10] But Congress neither expressed nor implied any such condition.

II. SECTION 271 DOES NOT REQUIRE COMPULSORY LICENSING OF USE PATENTS.

Neither the language nor the legislative history of section 271 of the Patent Act makes patent licensing compulsory as a condition of suing contributory infringers. Nor is any such requirement implied. As the Fifth Circuit correctly noted, "A general licensing obligation is foreign to [the] statutory scheme" (Pet. App. 177 n.27).

The text of section 271 nowhere mentions a requirement to license. Section 271(c) sets forth the elements of contributory infringement and section 271(d) declares that certain acts, including enforcement of the patentee's rights against contributory infringement, shall not constitute misuse. Petitioners and the United States as *amicus curiae* nevertheless contend that sections 271(c) and (d) imply an antitrust-type obligation to offer licenses to competitors before the patentee can sue contributory infringers. Yet the plain language of the

---

Justice Department ignored the fact that the misuse provision was limited to "contributory infringement as defined in the preceding parts of the bill," *i.e.*, to the sale of nonstaples. *1949 Hearings* 64-74; *see* note 4 *supra*.

[9] "The effect of this order compels the patent owner marketing unpatented, nonstaple components of his combination patent to first offer licenses to others marketing that component before it seeks equitable relief for contributory infringement" (Pet. App. 110 n.20).

[10] Ostensibly petitioners offer five alternatives for Rohm and Haas (Pet. Br. at 30-31). However, all but one of these alternatives—*i.e.*, licensing competitors—is impractical or impossible. *See* pp. 19-20 *infra*.

Patent Act belies this construction,[11] the legislative history mentions no such obligation, and Congress' long-standing patent policy cuts overwhelmingly against any notion of mandatory licensing.

The legislative hearings on contributory infringement clearly manifest that Congress intended discoverers of new uses to enjoy exclusive rights commensurate with those who synthesize new compounds or compositions of matter. *See 1948 Hearings* 4-5; *1949 Hearings* 67-73. Foremost among those rights is the exclusive right of patentees to reserve exclusive use of their inventions to themselves, and hence to refuse to license others. *See* 35 U.S.C. § 154; *Hartford-Empire Co.* v. *United States*, 323 U.S. 386, 432-33 (1945); *Continental Paper Bag Co.* v. *Eastern Paper Bag Co.*, 210 U.S. 405, 424, 429, 430 (1908). Congress never contemplated that the exclusive rights extended to those who discover new uses would be more limited in scope or subject to any obligations or exceptions not applicable to other patentees. In short, Congress in enacting section 271 expressed every intention of granting the owner of a method patent for using a nonstaple the same discretion to grant or withhold licenses as is available to any other patentee.

This construction is borne out by Congress' overall patent policy. As noted above, Congress has historically disfavored compulsory licensing of patents. Over the past century, it has consistently rejected numerous bills proposing a general obligation to license patents.[12] In

---

[11] The Fifth Circuit found petitioners' argument "an attractive possibility," but concluded it could "not discern it in the statute" (Pet. App. 177 n.27). *See* 35 U.S.C. § 154.

[12] *See Hartford-Empire Co.* v. *United States*, 323 U.S. 386, 417 & n.18 (1945) (citing S. 300, 45th Cong., 1st Sess. (1877); H.R. 8776, 62d Cong., 1st Sess. (1911); S. 2116, 62d Cong., 1st Sess. (1911); H.R. 26185, 62d Cong., 2d Sess. (1912); S. 2303, 77th Cong., 2d Sess. (1942); S. 2730, 77th Cong., 2d Sess. (1942); H.R. 1371, 78th Cong., 1st Sess. (1943)); S. 814, 94th Cong.,

those rare instances where Congress has required compulsory licensing, it has done so in narrowly defined fields implicating unique public policies.[13] But it has refused to require licensing in the vast majority of fields. In 1962, for example, Congress rejected a proposal to make mandatory the licensing of drug patents.[14]

Petitioners cite *Besser Manufacturing Co.* v. *United States*, 343 U.S. 444 (1952), and *United States* v. *Glaxo Group Ltd.*, 410 U.S. 52 (1973), as examples of court-imposed compulsory licensing for "patent abuses." But *Besser* and *Glaxo* both involved agreements among several patentees to restrict patent licenses in violation of section 1 of the Sherman Act. Section 271 does not sanction such agreements, but it does authorize individual method patentees to sell nonstaples used in the patented method and sue unlicensed sellers for contributory infringement. This Court has never required an individual patentee like Rohm and Haas to license competitors

---

1st Sess. (1975) (proposing general compulsory licensing to be administered by the Federal Trade Commission). *See generally* LEGISLATIVE REFERENCE SERVICE, COMPULSORY LICENSING OF PATENTS: A LEGISLATIVE HISTORY (Senate Patent Study No. 12, 1958).

[13] *See* Copyright Act, 17 U.S.C. §§ 101 *et seq.*; Air Pollution Prevention and Control Act, 42 U.S.C. §§ 1857 *et seq.*; Plant Variety Protection Act, 7 U.S.C. §§ 2321 *et seq.*

[14] In 1961, Senator Estes Kefauver sponsored amendments to the antitrust, patent, and drug laws which proposed, among other things, to cancel new drug patents after three years if the patentee refused to license all "qualified applicants" at a specific maximum royalty. S. 1552, 87th Cong., 2d Sess. § 3(d) (1962). After extensive testimony regarding the almost certain adverse impact of the compulsory licensing provisions on incentives for research and development, *see Drug Industry Antitrust Act: Hearings on S. 1552 Before the Subcomm. on Antitrust and Monopoly of the Senate Comm. on the Judiciary*, 87th Cong., 1st Sess. (1961), the Antitrust Subcommittee adopted several of the proposed drug amendments, but rejected a motion to approve the compulsory licensing provisions. *See* S. REP. NO. 1744, 87th Cong., 2d Sess., *reprinted in* [1962] U.S. CODE CONG. & AD. NEWS 2884, 2887.

merely because it has lawfully exercised its statutory patent rights, and it should not do so here.

Requiring method-of-use patentees to license competitors as a condition of enforcing their patent rights would take a devastating toll on medical and technological innovation in this country. We show below how this will occur in the area of pharmaceutical research, which today relies more than ever on the incentives of the patent system to justify the enormously expensive investigation of new therapeutic uses for previously ignored compounds.

III. THE FIFTH CIRCUIT'S HOLDING IS IMPORTANT FOR THE CONTINUED DISCOVERY OF NEW THERAPEUTIC DRUGS.

Because it is research intensive, the U.S. pharmaceutical industry relies heavily on the incentives of the patent system to research and develop new drugs. Despite the government's increased involvement in the investigation of new drugs, 91 percent of all new drugs are produced by private industry.[15] But the level of research and development in the industry is particularly sensitive to legal changes that affect the expected rate of return for pharmaceutical development. Primarily as a result of increased regulation, which has had the effect of increasing the costs of research and development and decreasing the effective patent life of new drugs, the rate of return in the industry has fallen in relation to that of other industries[16] and pharmaceutical innovation has slowed dramatically.[17] To withdraw the economic reward

---

[15] D. SCHWARTZMAN, INNOVATION IN THE PHARMACEUTICAL INDUSTRY 162 (1976).

[16] *Id.* at 136-61. *See* H. GRABOWSKI, DRUG REGULATION AND INNOVATION 39-44 (1976).

[17] H. GRABOWSKI, *supra* note 16, at 9, 17-37; Baily, *Research and Development Costs and Returns: The U.S. Pharmaceutical Industry*, 81 J. POL. ECON. 70 (1973); Peltzman, *The Benefits and Costs of*

for investigating new uses of known but unused compounds—as petitioners' and the district court's construction of section 271 would do—must similarly be expected drastically to curtail such research.

The public interest in developing new agents for the treatment of disease is equally great whether these agents are derived from new or from known, but unused, compounds. But if this Court were to adopt the position of petitioners and the district court, the resulting diminution of research in the latter area would deprive the public of this important source of therapeutic advances.

A. The Incentives to Pharmaceutical Innovation Are Currently in Decline.

The Drug Amendments of 1962 required for the first time that manufacturers demonstrate, prior to marketing, the effectiveness of a new drug for its intended use [18] and authorized the Food and Drug Administration (FDA) to regulate the testing procedure for new drugs.[19] *See United States* v. *Rutherford*, 442 U.S. 544 (1979). A striking, if unintended, effect of the Amendments was a dramatic decline in the number of new drugs marketed each year. In the pre-amendment years 1950-61, an average of 56 new drugs were introduced each year, but the average annual rate dropped to 17 in the years 1962-75.[20] Although this decline is not exclusively at-

---

New Drug Development, in REGULATING NEW DRUGS 113 (R. Landau ed. 1973) [hereinafter cited as *Benefits and Costs*]; Peltzman, *An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments*, 81 J. POL. ECON. 1049 (1973) [hereinafter cited as *Consumer Protection Legislation*].

[18] Pub. L. No. 87-781, §§ 102(b), 102(c), 21 U.S.C. §§ 355(b), 355(d).

[19] Pub. L. No. 87-781, § 106(b), 21 U.S.C. § 355(i).

[20] H. GRABOWSKI, *supra* note 16, at 18. *See also* Clymer, *The Changing Costs and Risks of Pharmaceutical Innovation*, in THE ECONOMICS OF DRUG INNOVATION (J. Cooper ed. 1969). Only a fraction—about ten percent—of the drop in new drugs can be attributed to the screening of ineffective drugs. *Benefits and Costs* at 161-70.

tributable to the elaborate administrative requirements established by the 1962 Drug Amendments, many studies agree that the Amendments have significantly retarded pharmaceutical innovation.[21]

This negative impact on new drug development can in large part be attributed to the increased risks and costs of research and testing and to the prolongation of the pre-marketing development period as a result of administrative regulation. Since the 1962 Amendments, only about one out of a thousand compounds isolated and tested for therapeutic value each year ultimately reaches the stage of clinical testing.[22] And among those that do reach clinical testing, only an average of 12 percent are ultimately approved by FDA for marketing.[23] When the costs of failure and foregone interest are taken into ac-

---

[21] *See* H. GRABOWSKI, *supra* note 16, at 17-37; *Benefits and Costs* at 161-70; *Consumer Protection Legislation* at 1054-56. This conclusion is borne out by studies comparing U.S. drug innovation with innovation abroad. Although the annual rate of drugs introduced in the U.S. declined by 53 percent between 1961 and 1973, the rate of drugs introduced abroad declined by only 28 percent for the same period. H. GRABOWSKI, *supra* note 16, at 2. Similarly, a comparison of the rate of growth in pharmaceutical research and development in the U.S. and other developed countries in the period 1969-72 indicates that the rate of growth in other developed countries was more than double the U.S. rate. Clymer, *The Economic and Regulatory Climate: U.S. and Overseas Trends*, in DRUG DEVELOPMENT AND MARKETING 137 (R. Helms ed. 1975). *See generally* W. WARDELL & L. LASAGNA, REGULATION AND DRUG DEVELOPMENT (1975); Wardell, *Therapeutic Implications of the Drug Lag*, CLINICAL PHARMACEUTICAL AND THERAPEUTICS, Jan. 1974, at 73-96.

[22] *See* D. SCHWARTZMAN, *supra* note 15, at 60.

[23] Hansen, *The Pharmaceutical Development Process: Estimates of Development Costs and Times and the Effects of Proposed Regulatory Changes*, in ISSUES IN PHARMACEUTICAL ECONOMICS 151, 155 (R. Chien ed. 1979).

count, the average cost of developing one new drug has been estimated to be approximately $74 million.[24]

Enhanced regulation has not only increased the costs of research and development, but also has substantially reduced the value of patent protection by decreasing the average *effective* patent life of new drugs. A pharmaceutical firm must, as a practical matter, apply for a patent as soon as a compound with potential therapeutic utility has been identified—*i.e.*, before the clinical testing period. Once a compound enters clinical testing, it is difficult to prevent other firms from copying the discovery and claiming priority of invention (either to invalidate the patent or claim it for themselves).[25] But applying before the clinical testing period means that the 17-year statutory period of patent exclusivity[26] commences well before FDA approves the drug for marketing.[27] Even if the regulatory review by FDA proceeds smoothly and expeditiously, the most recent studies of drugs approved in 1976-78 show that actual marketing of a new drug is on the average 6.8 years away when the firm obtains

[24] *Id.* at 151, 180. Hansen calculated this cost as $54 million in 1976 dollars. The $74 million figure is the same estimate in current dollars.

[25] *See* Kitch, *The Patent System and the New Drug Application: An Evaluation of the Incentives for Private Investment in New Drug Research and Marketing*, in REGULATING NEW DRUGS 82, 85 (R. Landau ed. 1973) [hereinafter cited as *Patent System and NDA*]. In theory, the discovering firm might conduct its clinical testing in secret, but it is difficult to envision this as a practical matter. In any event, one of the principal purposes of the patent system is to encourage early disclosure of scientific innovations, which reduces wasteful duplication of research and encourages further advances in the field. *Id.* at 85-86; *see Sinclair & Carroll Co.* v. *Interchemical Corp.*, 325 U.S. 327, 331 (1945); REPORT OF THE PRESIDENT'S COMMISSION ON THE PATENT SYSTEM 2-3 (1966).

[26] 35 U.S.C. § 154.

[27] D. SCHWARTZMAN, *supra* note 15, at 163; *Patent System and NDA* at 85-86.

its patent.[28] Hence, the average effective life of drug patents is now only 10.2 years,[29] and the trend over the last fifteen years strongly suggests that it will continue to decline.[30]

The increased costs and diminishing patent protection for new drugs have, in turn, substantially reduced the expected rate of return for investment in pharmaceutical research and development. Two studies of rates of return after the 1962 Drug Amendments conclude that the expected rate of return for drug research and development has fallen significantly below the expected rate for most other industries.[31] As a consequence, the number of research projects undertaken by the industry has declined significantly[32] and many U.S. firms have shifted substantial segments of their development activities to countries that regulate the development period less stringently.[33]

[28] *See* CENTER FOR THE STUDY OF DRUG DEVELOPMENT, PATENT DATA—1976-78 U.S. NCE APPROVALS (Annual Surveys 1978-80).

[29] *Id.* Professor Kitch concludes that "the effect of the complex marketing clearance procedures has been to reduce the effective period of patent protection, and, correspondingly, the private investment likely to be made in the detection, development, and marketing of new drugs." *Patent System and NDA* at 86.

[30] The average effective patent life of new drugs previously fell by 1.5 years—or 10.8 percent—from an average of 13.9 years in 1966-69 to only 12.4 years in 1970-73. D. SCHWARTZMAN, *supra* note 15, at 173. The most dramatic decline occurred in the field of cardiovascular drugs, for which the average patent life dropped 10.1 years—or 65.4 percent—from 15.4 to 5.3 years. *Id.*

[31] D. SCHWARTZMAN, *supra* note 15, at 136-61; Clymer, *The Economics of Drug Innovation*, in THE DEVELOPMENT AND CONTROL OF NEW PRODUCTS (M. Pernarowski & M. Darrack ed. 1971).

[32] Sarett, *FDA Regulations and Their Influence on Future R&D*, RESEARCH MANAGEMENT, March 1974, 18-20.

[33] Lasagna & Wardell, *The Rate of New Drug Discovery*, in DRUG DEVELOPMENT AND MARKETING 155 (R. Helms ed. 1975). Lasagna and Wardell surveyed the fifteen largest firms in the industry, which

B. Reversal of the Fifth Circuit's Holding Would Substantially Curtail Discovery and Development of New Therapeutic Uses For Known, Nonstaple Compounds.

Because of the decreasing incentives to research and development in the pharmaceutical industry, the industry relies heavily on the patent system to justify the growing costs of drug development. In this precarious environment, requiring owners of patents for the use of nonstaple compounds to offer licenses to competitors will substantially curtail new use research. It amounts to granting the right of exclusivity inherent in a patent with one hand while withdrawing it with the other.

PMA members are currently engaged in screening unpatented, nonstaple compounds for possible new therapeutic applications, and several now hold method-of-use patents for such compounds.[34] Before the district court's decision in this case, there was good ground for believing that section 271 did not require the discoverer of a new therapeutic use for a nonstaple compound to license its competitors. The decision of the district court, however, cast doubt on the freedom of patentees to obtain relief against contributory infringement where competitor licenses had not been offered.[36] The Fifth Circuit properly reversed and thereby restored the incentive so clearly

---

account for over 80 percent of research and development in the industry. Their survey reveals that the number of drugs tested abroad increased substantially between 1966 and 1974. By 1974, one half of all new substances were tested abroad. *Id.* at 157-58.

[34] For example, PMA members hold patents for the use of unpatented, nonstaple compounds in the treatment of gout, tuberculosis, arthritis, pain, and hypertension. PMA members engaged in screening unpatented, nonstaple compounds currently test for many potential therapeutic applications, most commonly cardiovascular, anti-infective, analgesic, and cancer chemotherapy.

[35] *See* note 9 *supra* and accompanying text.

intended by section 271 to investigate and market new uses for known, nonstaple compounds.[36]

Petitioners contend that compulsory licensing is not the sole alternative to the Fifth Circuit's affirmation of the patentee's right to sell nonstaples used in the patented method while refusing to license competitors. They suggest essentially three alternatives to compulsory licensing: the patentee could (1) license consumers directly to practice the patented method, (2) license professionals to practice the method, or (3) itself practice the method (Pet. Br. at 30-31).

Each of these alternatives is impractical and, we think, ultimately would disserve consumers. In the instant case, the transaction costs of expressly licensing thousands of farmers would raise the price of propanil substantially, and without any corresponding enhancement of research and development incentives. In contrast, commercialization of the patented discovery through sales carrying implied licenses does provide the reward for invention which the patent laws are intended to provide, and thus encourages the development of useful applications for otherwise previously unused compounds.

Licensing both professionals and consumers to administer propanil would only partially alleviate the problems of licensing only consumers. And licensing only professionals to administer the compound would raise the costs of spraying crops for those who would otherwise choose to spray their own fields. The same would be true if Rohm and Haas chose to spray propanil on crops itself. Moreover, in applying the compound itself, Rohm and Haas would exclude local spraying companies from the market, hardly a result compatible with the procompetitive philosophy petitioners espouse.

Petitioners' marketing alternatives are even more impractical for the pharmaceutical industry. Expressly li-

---

[36] *See 1948 Hearings* 3-5.

censing millions of consumers or hundreds of thousands of physicians—even if it could realistically be done—would raise the price of drugs substantially, and perhaps out of reach, again with no augmented incentive to innovation. Plainly, there is no separate market for licensing users of the patented method apart from the sale of the nonstaple component. And neither of petitioner's last two alternatives is feasible for commercializing patents covering the use of drugs, since neither the manufacturer nor an intermediary distributor can be said to "use" the drug.

In short, if the Fifth Circuit's construction of section 271 is rejected, the only practical alternative is compulsory licensing of competitors. But compelling discoverers of new beneficial uses of nonstaple articles to license their discoveries would be self-defeating. By withdrawing the inventor's right to sell the nonstaple article and to withhold licenses from would-be competing sellers of the nonstaple, innovators will be denied any practical means for obtaining the reward for their invention contemplated by the patent system. To the extent that such reward is unavailable, the incentive to investigate and develop new therapeutic uses of nonstaple compounds will be diminished.[37]

This effect is magnified in the drug industry by the requirements of the maximum allowable cost (MAC) regulations promulgated by the Department of Health, Education and Welfare (HEW). These regulations provide for the establishment of ceilings on the maximum cost for "multi-source drugs"—*i.e.*, drugs sold by two or more companies—reimbursed under federal Medicare and state

[37] *See* J. MARKHAM, PATENTING AND LICENSING POLICY AND PRIVATE SECTOR PARTICIPATION IN ENERGY RESEARCH AND DEVELOPMENT App. 2-3 (1977) (prepared under an Energy Research and Development Administration contract); D. SCHWARTZMAN, *supra* note 15, at 158.

health programs.[38] If innovators are required to license others to sell a nonstaple drug, under present HEW policy the drug will be deemed a "multi-source drug" and therefore subject to the MAC limitations.[39] By thus limiting the price that an innovator may obtain for a new drug in this increasingly important segment of the market, the MAC program must be recognized as further reducing the available rate of return on discoveries of new uses[40] and consequently magnifying the disincentive to innovation that compulsory licensing would create.

A reduction in the expected rate of return for developing new uses is likely to redirect investment elsewhere.[41] Because, as noted, it costs on the average $74 million to investigate and develop a new drug, pharmaceutical firms are particularly sensitive to changes in the expected rate of return for various types of research. Manufacturers cannot afford to risk such substantial investment in investigating new uses of previ-

[38] *See* 45 C.F.R. §§ 19.1-19.6 (1979). The regulations also cover the maximum allowable costs for drugs purchased under "projects for health services," *id.* § 19.1(a)(3), and non-research drug procurements by HEW or its contractors, 41 C.F.R. § 3-4.6104-2 (1979). The maximum reimburseable cost is determined by the "lowest unit price at which the drug is widely and consistently available." 45 C.F.R. § 19.5(c) (1979).

[39] A MAC was set for doxepin hydrochloride, an anti-anxiety drug, when the patentee licensed just one other firm to manufacture and sell the drug. 43 Fed. Reg. 57972 (1978). In a currently ongoing case, *Pfizer, Inc.* v. *Califano*, Civ. No. 79-0185 (D.D.C. Jan. 23, 1979), a preliminary injunction against implementation of that MAC was denied.

[40] *See* D. SCHWARTZMAN, *supra* note 15, at 327-31.

[41] *See* J. MARKHAM, *supra* note 37, App. 2-3; D. SCHWARTZMAN, *supra* note 15, at 158. Schwartzman indicates that "a lower rate of return will tend to divert investment elsewhere. Thus, a reduction in the protection offered by patents will reduce the profit rate from investment in R&D only temporarily; it will encourage the industry to reduce the quantity of its investment in R&D and thereby raise the profit rate on R&D." *Id.*

ously ignored, and perhaps therapeutically promising, substances if they promise a lower rate of return than new, patentable compounds. As a consequence, however, many previously ignored compounds with promising but untested therapeutic value will continue to be ignored.

In light of the diminishing incentives for research and development in the industry, particularly the substantial reduction in the effective life of drug patents, the Court should hesitate to construe the scope of patent protection in a manner that will further reduce incentives to develop new therapeutic uses for known but undeveloped compounds. If further disincentives to innovation are to be created as the price of pursuing other public policy objectives, Congress and not this Court is the proper forum for undertaking this rebalancing of competing claims. As noted above, if there is a basic theme to the legislative history of section 271, it is Congress' strong desire to encourage development of useful applications for known but previously undeveloped compounds. The construction urged on this Court by petitioners and the United States would frustrate that plain legislative purpose.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

PHILIP ELMAN
JOEL E. HOFFMAN
WILLIAM R. WEISSMAN
CAREY R. RAMOS
WALD, HARKRADER & ROSS
1300 Nineteenth St., N.W.
Washington, D.C. 20036

Attorneys for Pharmaceutical Manufacturers Association, Amicus Curiae

BRUCE J. BRENNAN
EDWIN C. MULCAHY, JR.
1155 Fifteenth St., N.W.
Washington, D.C. 20005

Of Counsel

March 21, 1980

APPENDIX

1948 Hearings

[3]

MEMORANDUM ON H.R. 5988 (80th CONG., 2D SESS.), SUBMITTED BY THE NEW YORK PATENT LAW ASSOCIATION

* * *

[4]

THE NEED FOR THE STATUTE

The need for a statute reviving the expression of law and morals contained in the doctrine of contributory infringement is apparent from the effect of the Supreme Court decisions. By them, two important classes of invention have been taken outside the protection of the patent law.

Discovery of new uses. "Discoveries" by inventors are the only subject matter of patents mentioned in the constitutional provision on which our patent law is based [footnote omitted]. The finding of a new and unsuspected property of an old thing or substance which enables it to do something which could not before be accomplished is a type of discovery which in the past has done much to promote the useful arts. Such discoveries by inventors have long been protected by method or process patents under the provisions of the statute permitting the patenting of new arts.

[5]

In chemical research, a new and commercially important result is not infrequently obtained by the use of

chemical compounds which have previously existed but have not been put to any practical use. A chemist seeking to solve some practical problem may discover that the result which he is seeking may be achieved by the use of a chemical compound which has a peculiar property not previously suspected. The practical importance of his discovery, and the practical advance which he has made in the art, are not affected by the question of whether or not the required chemical compound had previously been made. In view of the many years of diligence of German chemists and chemical students in making in their laboratories innumerable chemical compounds, regardless of any possible value to the compounds, it is altogether probable that, after a modern chemist has discovered how to solve a practical problem by the use of an unknown property of some chemical, he will find somewhere in the chemical literature a description of the compound which he has found necessary for this purpose. Under these circumstances, the patent which he obtains must be in the form of a process or method.

Before the recent Supreme Court decisions, such patents could be effectively enforced under the doctrine of contributory infringement, since anyone who manufactured and distributed a chemical for the sole and obvious purpose of causing infringement of a method patent is clearly a contributory infringer of the patent.

Under the recent Supreme Court decisions, new-use inventions which are most widely used, and therefore most important, are, as a practical matter, placed outside the protection of the patent law. The decisions prevent the patentee from obtaining relief against the person who is guilty of causing infringement of the patent and leave him only the right to recover against innocent members of the public who have been induced to use the patented process. Thus, the effect of the decisions is to protect the guilty and encourage suits against the inno-

cent. As a practical matter, no patentee can afford to attempt to protect . . . his invention by suing all the innocent members of the public who have been induced to use it. Thus, those who have made new-use inventions receive no reward for the advance which they have made in the art, and the stimulus of the patent system is withdrawn from this class of inventions.